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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,287	07/15/2003	Patrick J. Sweeney	029815-0102	7722

23524 7590 11/26/2007  
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EXAMINER
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KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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11/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/620,287	<b>Applicant(s)</b> SWEENEY, PATRICK J.	
	<b>Examiner</b> Christopher D. Koharski	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/26/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the RCE filed 9/29/2007 in which claims 1 and 13 were amended. Currently claims 1-17 are pending for examination in this application.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) that was submitted on 9/26/2007 is partially in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering part of the information disclosure statement. Concurrent with the standards set forth under 37 CFR 1.97, references must cited under the proper guidelines (i.e. not reference to an office action) and additional references must be submitted and supported.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C 103(a) as being unpatentable over Wilcox et al. (US5,681,289) in view of Sasso et al. (US2004/0225292) (or Chappius (US2001/0021852). Wilcox et al. discloses a chemical dispensing system.

Regarding claims 1-17, Wilcox et al. discloses a device (87,105) for delivering a substance to a bone (85), the device comprising: a bone rod (87,105) used for fixation comprising two ends connected by a shaft, wherein the shaft is cannulated (88) along a portion of its length; one or more fenestrations (90,109) disposed along the cannulated portion of the bone rod shaft; an insert (100,110) disposed inside the cannulated bone screw, wherein the insert comprises two end connected by a shaft and is cannulated (103) along at least a portion of its length; and one or more fenestrations (105,112) disposed along the cannulated portion comprising a permeable section of the insert to provide a delivery pathway for a substance between at least one end of the bone screw (89, 96) (Figures 8-10) (Figures 11-13). Wilcox et al. also discloses multiple embodiments in which reservoirs are present: an external tube (91), pump (127) or subcutaneous pump (62) in which the therapeutic fluid can be introduced into the system (Figures 6, 9 and 14).

Sasso et al. (or Chappius) meets the claim limitations as described above except for the bone screw and specific materials.

However, Sasso et al. teaches a bone anchor and methods of using the same and Chappius teaches a fenestrated surgical screw and method.

Regarding claims 1-17, Sasso et al. teaches a device (10) for delivering a substance to a bone comprising a bone screw (12) comprising two ends (12a, 22) connected by a shaft wherein the shaft (30) is cannulated along a portion of its length, one or more bone-screw fenestrations disposed along its length to provide a delivery pathway for substance through the bone-screw (Figures 1-12). Additionally, the screw is self tapping ([0023]) and the screw is composed of various alloys ([0033]), and the screw is capable of being used for fixation (Figure 12). Sasso et al. further discloses a substance reservoir (5) attached to the end of the bone screw (Figure 5).

Regarding claims 1-17, Chappius teaches a device (10) for delivering a substance to a bone comprising a bone screw (Figure 1) comprising two ends (14, 16) connected by a shaft wherein the shaft (near 22) is cannulated (22) along a portion of its length, one or more bone-screw fenestrations (24) disposed along its length to provide a delivery pathway for substance through the bone-screw (Figures 1-10). Additionally, the screw is self tapping (Figure 2) and the screw is composed of various alloys ([0027]), and the screw is capable of being used for fixation (Figure 12). Chappius further discloses a substance reservoir (Figures 8-9) attached to the end of the bone screw.

At the time of the invention, it would have been obvious to add the spiral grooves of Sasso et al. (24) or Chappius (22) in order better fix the rod into the bone and allow for better bone healing. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Sasso et al. ([0001-0014]) or Chappius ([0001-0013]).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

11/17/07



Christopher D. Koharski  
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